

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC. and
BAXTER HEALTHCARE CORPORATION,

Defendants.

BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Counterdefendants.

Civil Action No. 05-349-GMS

Jury Trial Demanded

PUBLIC VERSION

**DEFENDANTS' MOTION *IN LIMINE* NO. 3 TO BAR DR. RAVETCH FROM
TESTIFYING REGARDING INFRINGEMENT UNDER THE
DOCTRINE OF EQUIVALENTS**

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Defendant Baxter International Inc. and Defendant/Counterclaimant Baxter Healthcare Corporation (collectively "Baxter"), submit this motion *in limine* to strike the unsupported portions of Dr. Ravetch's Expert Report regarding infringement under the doctrine of equivalents and to bar testimony from Dr. Ravetch concerning the same. For the reasons discussed below, this motion should be granted.

I. STATE OF THE PROCEEDINGS AND SUMMARY OF THE ARGUMENT

Talecris Biotheapeutics, Inc. and Bayer Healthcare LLC (collectively "Plaintiffs") sued Baxter, alleging infringement of U.S. Patent No. 6,686,191 (the "'191 patent"). Talecris has alleged, *inter alia*, that Baxter's process for making GAMMAGARD® Liquid infringes the '191 patent under the doctrine of equivalents.

In his expert report, Dr. Jeffrey Ravetch, plaintiffs' infringement expert, opines that Baxter infringes certain claims under the doctrine of equivalents. (Rogaski Decl. Ex. 7 at ¶¶ 78-79, 83, 85, 89-90, 94, 97, 100.) However, that report contains no support for his superficial opinions that (1) the ionic strength of GAMMAGARD® Liquid is equivalent to the claimed ionic strength or (2) the osmolality of GAMMAGARD® Liquid is equivalent to the tonicity levels claimed in the '191 patent. As these opinions are based merely on speculation, they do not meet the threshold standards of Rule 702 and *Daubert*. See Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Therefore, these opinions regarding infringement under the doctrine of equivalents should not be admitted into evidence through either the report or the testimony of Dr. Ravetch.

II STATEMENT OF FACTS

With regard to Claim 10 of the '191 patent, which limits the ionic strength of the incubated

solution to less than about 0.001M,¹ Dr. Ravetch opined that

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(Rogaski Decl. Ex. 7 at ¶ 78.) Dr. Ravetch also opined that

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(*Id.* at ¶ 79.) However, neither Dr.

Ravetch nor any of Talecris' other expert witnesses, nor the named inventor of the '191 patent, tested the effect of ionic strength in the claimed incubation step. Indeed, Dr. Ravetch's opinion is devoid of **any** actual comparison of the effect of the ionic strength of the GAMMAGARD[®] Liquid to the effect of ionic strength in a solution with an ionic strength of less than 0.001 M. Dr. Ravetch's opinion regarding Baxter's infringement of Claim 10 under the doctrine of equivalents is merely *ipse dixit*.

With regard to the tonicity requirement of Claims 12 and 15-18², Dr. Ravetch opined that

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and that

REDACTED

(*Id.* at ¶83.) Dr. Ravetch also opined that REDACTED

¹ Claim 10 depends on Claim 1 and further requires: "wherein the ionic strength is less than about 0.001M." (Rogaski Decl. Ex. 8 at Col. 12:10-11.)

² Claim 12 also depends on Claim 1 and Claims 15-18 further depend on at least Claims 1 and 12. These claims contain limitations on "the tonicity of the solution," including "a physiologic value" (Claim 12), "about 230 to about 490 mosmol/kg solvent" (Claim 15) or "about 274-309 mosmol/kg solvent" (Claim 16). (Rogaski Decl. Ex. 8 at Col. 12:14-17, 22-30.)

REDACTED

(*Id.* at ¶89.) However, neither Dr. Ravetch

nor any of Talecris' other expert witnesses made **any** measurements of the tonicity of GAMMAGARD[®] Liquid. In addition, Dr. Ravetch's report contains no data or scientific references to support his opinion that tonicity and osmolality are equivalent or that the osmolality of GAMMAGARD[®] Liquid performs the same function, in the same way, to produce the same result as the claimed tonicity.

II. ARGUMENT

An expert witness must expressly state the factual bases for any opinion testimony in an expert report. Fed. R. Civ. P. 26(a)(2)(B) (an expert's report "shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor . . . [and] the data or other information considered by the witness in forming the opinions.") In addition, under Rule 702, expert opinion testimony is admissible only when "(1) the **testimony is based upon sufficient facts or data**, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702 (emphasis added). Dr. Ravetch's opinions regarding infringement under the doctrine of equivalents are not based on **any** facts or data, as he included no basis for these opinions in his report. Furthermore, under Rule 26(a)(2)(B), this omission cannot be cured by the tardy assertion of a basis for Dr. Ravetch's opinions. *See* Fed. R. Civ. P. 26(a)(2)(B).

A. Judicial Interpretation of the Requirements for Admissibility of Expert Opinion Testimony

In *Daubert*, the U.S. Supreme Court established the judicial standard for the admissibility of expert testimony:

Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.

509 U.S. at 592. Under the "scientific knowledge" prong of the *Daubert* analysis, "[p]roposed testimony must be supported by appropriate validation — i.e., 'good grounds,' based on what is known." *Id.* at 590. An expert's opinion is not admissible if it is based on "subjective belief or unsupported speculation". *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741, 742 (3d Cir. 1994) (quoting *Daubert*, 509 U.S. at 590). Thus, district courts must act as gatekeepers to ensure the exclusion of unreliable expert testimony. *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 320-21 (3d Cir. 2003); *United States v. Trala*, 162 F. Supp. 2d 336, 345 (D. Del. 2001) (*Daubert* directs judges to ensure that evidence presented by expert witnesses is relevant, reliable, and helpful to the jury) (Sleet, J.). However, a threshold analysis of the reliability of Dr. Ravetch's opinions on infringement under the doctrine of equivalents is impossible, because he has included no basis for these opinions in his report.

B. Requirements for Proving Infringement Under the Doctrine of Equivalents

To prove infringement under the doctrine of equivalents, a patentee must show that the accused device or process "performs substantially the same function in substantially the same way to obtain the same result" as the claimed device or process. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 172 U.S. 605, 608 (1950) (internal citations omitted). *Graver Tank* analysis requires that the patentee present particular evidence as to the substantial equivalence of the function, means and result, without which "a jury is more or less put out to sea without guiding charts when called upon to determine infringement under the doctrine." *Lear Siegler, Inc. v. Sealy Mattress Co. of Michigan, Inc.*, 873 F.2d 1422, 1425-26 (Fed. Cir. 1989); accord *nCUBE Corp. v. Seachange Int'l, Inc.*, 313 F. Supp. 2d 361, 376-78 (D. Del. 2004) (Farnan, J.). This evidentiary requirement assures that "the fact-finder does not, under the guise of applying the doctrine of equivalents, erase a plethora of meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement." *Texas Instruments*

Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996) (internal citations and quotation marks omitted). As Dr. Ravetch's opinions regarding infringement under the doctrine of equivalents are merely *ipse dixit*, these opinions are insufficient to support a finding of infringement. *Lear Siegler*, 873 F.2d at 1425-26; *Graver Tank*, 172 U.S. at 608.

IV CONCLUSION

Dr. Ravetch's opinions regarding infringement under the doctrine of equivalents are inadmissible because they are "unsupported speculation" with no factual foundation. *See Daubert*, 509 U.S. at 590. In addition, these opinions are insufficient to prove infringement under the doctrine of equivalents. *See Lear Siegler*, 873 F.2d at 1425-26. Consequently, the Court should strike Dr. Ravetch's opinions regarding equivalents and prohibit him from testifying at trial with regard to infringement under the doctrine of equivalents.

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CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on April 28, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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